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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,690	03/03/2005	Matti Siren	18593	5282

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,690	SIREN, MATTI	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *10,13-16,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/15/08, 11/20/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

To summarize the current election, applicant elected Group 1 and the species of stents coated with D-3,4,5-tri-O-(phenylcarbamoyl)myoinositol-1,2,6-triphosphate.

Based on this election, new claims 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Specification

The amendment filed September 15, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: 1) the replacement of Y^8 with Y^9 in the definition of V^1 to V^4 and 2) the addition of an additional Y variable, namely Y^{24} (see 35 USC 112 first paragraph rejections of claims 2-9,11, and 17 below for further detail).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-9, 11, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In the original disclosure and the priority document, the radical designated in section b of claim 2 required that the atoms of V^3 and V^4 that connect to the phosphorus atom be the same as each other since this atom for each was recited to be Y^8. This means that three of the four atoms attached to the phosphorous would be the same as one another. For example, if Y^8 were oxygen for a given phosphorus containing radical, then the atom attached via a double bond to the phosphorus and the atom/point of attachment for both V^3 and V^4 to the phosphorous atom would also be oxygen. The amendment to claim 2 changes the recitation of V^3 and V^4 such that their point of attachment is now Y^9 and is now able to be different than the atom attached to the phosphorous via a double bond (Y^8). With this amendment, if Y^8 is oxygen and Y^9 is sulfur, as is possible given the recitations for the various Y atoms, the resulting molecule does not appear in the disclosure as filed or in the priority document. In addition, there is no written basis for an additional Y variable, namely Y^{24}. Further, there is also no written basis for the new recitation that 1) Y^1 to Y^{24} are different and independently selected from NR^{10}, NOR^{11}, O, or S; 2) R^1 to R^{11} are different and independently selected from the recited options i-v; 3)o1 to o3 are independently 0 or 1;

and 4) m1 to m7 are independently 0 or 1. There is basis for the specific compounds named that fulfill recitations 1-4, detailed above, but not the entire genus now recited.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is in conflict with the recitation of its parent claim (claim 2). Briefly, the point of atom attachment of V^1 and V^2 to the phosphorous atom have to be the same atom according to claim 2. Claim 3 now presents the option that the point of attachment of V^1 and V^2 to the phosphorous atom are different atoms (one can be a carbon while the other can be an oxygen).

Claim 18 does not define all the variables used in its depicted structure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Persson et al. (U.S. Patent No. 5,866,557) in view of Chudzik et al. (U.S. PGPub No. 2002/0032434).

Persson et al. teach a collection of inositoltriphosphate compounds that are used to treat inflammatory conditions (see title and abstract). Persson et al. go on to teach particular pathologies, including inflammatory conditions caused by injuries due to or following surgery and operations with grafts and catheters, that the taught compounds are envisioned to treat as well as generally teach that that the compounds are effective against conditions in which inflammation occurs (see column 1 lines 58-62 and column 2 lines 1-3; instant claim 1). Further, Persson et al. specifically teach D-3,4,5-tri-O-(phenylcarbamoyl)myoinositol-1,2,6-triphosphate as a particularly envisioned compound in the invention (see example 5; instant claims 1-9 and 17-18). Persson et al. do not specifically teach the incorporation of their compounds into a stent coating.

Chudzik et al. teach a stent coated with a mixture of polymer and a bioactive agent to counteract the restenosis and inflammation that occurs when the device is

placed in the body (see paragraph 3, 17, 28 and claim 21). In particular, Chudzik et al. teach anti-inflammatory compounds as bioactive agents to include in the stent coating (see paragraph 25 lines 12-13). Since the particular compounds of Persson et al. are taught to be useful in ameliorating inflammation in general and when due to or after surgeries that involve the use of grafts (stent) or catheters, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use their taught D-3,4,5-tri-O-(phenylcarbamoyl)myoinositol-1,2,6-triphosphate in the stent coating of Chudzik et al. Therefore claims 1-9 and 17-18 are obvious over Persson et al. in view of Chudzik et al.

Claims 1-3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Persson et al. in view of Chudzik et al. as applied to claims 1-9 above, and further in view of Shvets (Russian Chemical Reviews 1974 43:488-502).

Persson et al. in view of Chudzik et al. make obvious a stent coated with D-3,4,5-tri-O-(phenylcarbamoyl)myoinositol-1,2,6-triphosphate (see instant claims 1-3). This modified reference does not teach that the phosphate groups are positioned such that one is axial and two are equatorial in this compound.

Shvets teaches the stereochemistry of myoinositol derivatives and that the most stable conformational form of myoinositol has one axial hydroxyl group at the 2 position and the remaining hydroxyl groups placed equatorial (see page 88 column 2 paragraph 1 lines 1-6; instant claim 11). The same stereochemistry is taught for phosphated versions of the compound (see page 496 scheme 16; instant claim 11). It is therefore

the examiner's position that based upon the teachings of Shvets, D-3,4,5-tri-O-(phenylcarbamoyl)myoinositol-1,2,6-triphosphate would have its phosphate groups located such that two were equatorial and one was axial. Therefore claims 1-3 and 11 are obvious over Persson et al. in view of Chudzik et al. and Shvets.

Response to Arguments

Applicants' arguments, filed November 20, 2008, have been fully considered but they are not deemed to be persuasive. Applicant argues that because Perrson et al. exemplify the compounds of their invention being tested on oedma and Chudzik et al. do not teach how to screen or select a compound for use in their stent coating, the claims are not obvious over the combination of these two references. Perrson et al. teach that the anti-inflammatory compound of their invention are effective against tissue damage and particularly name injuries caused by or following surgery of grafts and catheters, indicating that vascular injury due to surgery was envisioned (see column 1 lines 61-62). Restenosis is one such very well known result of vascular injury due to surgical intervention. In addition, Perrson et al. also teach that conditions and tissue damage where inflammation occurs are also envisioned (see column 2 lines 1-3). Here again, restenosis is one such condition. Further, Chudzik et al. specifically teach anti-inflammatory agents as bioactive agents contemplated as being included in their device and also contemplate the utility of their device for issues of inflammation and restenosis that occur due to surgical intervention with vascular implants (stent) (see paragraphs 3 and 25). Chudzik et al. therefore does provide guidance as to which bioactives are

considered or should be selected and which pathological conditions they. Thus as a known option within the technical grasp of one of ordinary skill in the art at the time of the invention, it would have been obvious to employ the compounds or Perrson et al. and in particular those that were exemplified in the device of Chudzik et al. Furthermore, the recitation of the claims that the device is intended for particular uses does not confer any structural limitation to the product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The device that would be obvious based on the teachings of Perrson et al. and Chudzik et al. would have the claimed capabilities.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615